News Release

Santen Provides Update on EU Marketing Authorization Application for DE-109 (Sirolimus)

May 11, 2016, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) today announced that it plans to withdraw and later resubmit its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the use of DE-109 as a treatment of patients with chronic noninfectious uveitis of the posterior segment (NIU-PS) in the European Union.

From discussions with the Committee for Medicinal Products for Human Use (CHMP) of the EMA, Santen understands there to be a clear and unmet medical need for DE-109 as evidenced by earning orphan drug status. Though the original application was filed based on the data of a single phase III SAKURA (Sirolimus study Assessing double-masKed Uveitis tReAtment) Study 1, Santen acknowledges the EMA's preference to wait for data from the second phase III study, SAKURA Study 2, before granting marketing authorization. After SAKURA Study 2 is complete, Santen intends to resubmit an application for DE-109 with the EMA as well as seek approvals on a worldwide basis with the data from the two global phase III studies.

The impact of the aforementioned plans on forecasts for the fiscal year ending March 31, 2017 is not material.

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About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, sales, and marketing of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in over 50 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see Santen's website (www.santen.com).

Santen Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and

other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

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